NACDS

National Association of Chain Drug Stores

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President & CEO

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: Proposed Rule for Citizens Petitions -- Docket No. 99N-2497

Ladies and Gentlemen:

The National Association of Chain Drug Stores (NACDS) is pleased to submit these comments regarding a new rule limiting citizens petitions, which was recently proposed by the Food and Drug Administration (FDA). See 64 Fed. Reg. 66822 (Nov. 30, 1999). Provisions in the proposed rule would prohibit innovator pharmaceutical manufacturers from filing citizens petitions to delay marketing of approved generic drugs.

NACDS membership consists of 146 retail chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 94,000 pharmacists. The chain community pharmacy industry is comprised of more than 19,000 traditional chain drug stores, 7,000 supermarket pharmacies and 5,000 mass merchant pharmacies. Chain operated community retail pharmacies fill over 60% of 3 billion prescriptions dispensed annually in the United States.

NACDS supports the proposed rule. Innovator drug manufacturers have often used citizen petitions to delay competition from generic drugs. In fact, the HHS Office of Inspector General found that 30 percent of all citizen petitions were filed to evade generic pharmaceutical competition.

After FDA has approved an Abbreviated New Drug Application (ANDA) for a new generic product, an innovator drug manufacturer will often file a citizen petition challenging the FDA approval. The petition is filed for purposes of delay. Several months are needed for FDA to review and act on the petition. During those months, the innovator manufacturer avoids competition. The result is delayed access to consumers of lower priced, equally effective versions of brand name drugs.

Eliminating regulatory delays in generic drug approval, the proposed rule will foster competition in the marketplace. Once a generic drug product satisfies the strict standards for approval of an ANDA, citizen petitions should not further delay the generic product's introduction to the marketplace.

Thank you for considering our comments. If you have any questions, please contact John Coster, Vice President of Federal and State Programs, at (703) 549-3001.

Sincerely,

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Senior Vice President and General Counsel

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